

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 7/00	A1	(11) International Publication Number: WO 99/44552 (43) International Publication Date: 10 September 1999 (10.09.99)
(21) International Application Number: PCT/IL99/00059 (22) International Filing Date: 29 January 1999 (29.01.99) (30) Priority Data: 123573 5 March 1998 (05.03.98) IL 126783 27 October 1998 (27.10.98) IL (71) Applicant (for all designated States except US): M.T.R.E. ADVANCED TECHNOLOGY LTD. [IL/IL]; Industrial Park, P.O. Box 3582, 38900 Caesaria (IL). (72) Inventor; and (75) Inventor/Applicant (for US only): KUSHNIR, Igal [IL/IL]; Shekedim Street, 37000 Pardes Chana (IL). (74) Agent: REINHOLD COHN AND PARTNERS; P.O. Box 4060, 61040 Tel-Aviv (IL).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: SYSTEM AND METHOD FOR HEAT CONTROL OF A LIVING BODY		
<p>The diagram illustrates a system for heat control of a living body. A person (80) is lying on a table. A heat exchanger unit (220) is placed on the person's back. Wires connect this unit to a control system located beneath the table. The control system consists of a pump (107) and a heat exchanger (106). A sensor (98) is connected to the heat exchanger (106). A power source (96) is also connected to the system. A control module (94) is also part of the system.</p>		
(57) Abstract <p>A system and method for controlling an individual's body and temperature are provided. The system comprises a heat exchanger for transferring heat to or removing heat from portions of the individual's body surface, at least one BCT-sensing device for measuring the individual's actual BCT (aBCT) and emitting an aBCT data signal, at least one sensing device for measuring a parameter indicative of the heat transfer dynamics (HTD) between the body surface and the body's core, and emitting an HTD data signal, and a control module for receiving data signal from measuring devices, comprising the aBCT data signal and the HTD data signal, and for emitting a control signal for controlling heat exchange properties of the heat exchanger as a function of the data signals and a desired body core temperature (dBCT).</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

SYSTEM AND METHOD FOR HEAT CONTROL OF A LIVING BODY

FIELD OF THE INVENTION

The present invention concerns a system and method for thermoregulations of a living body. The system and method of the invention may be applied to both humans and animals.

5 BACKGROUND OF THE INVENTION AND PRIOR ART

A living body can maintain a normal body temperature, which in humans is about 36.5-37°C, under normal conditions. However, when subjected to extreme temperature conditions or to a variety of medical treatments, the body may not be able to properly regulate the body
10 temperature. This is the case, for example: in individuals exposed to extreme temperatures; and in a variety of physiological disorders and medical conditions (e.g. general anesthesia) where the body loses its ability to properly regulate the body temperature.

Hypothermia is a reduction in body temperature which may result from
15 exposure to a cold environment. Mild hypothermia in which body's core temperature (namely the temperature of internal organs and tissue within the body) is reduced by about 2°C below the normal temperature, commonly occurs during and following surgery that is conducted under general anesthesia, as patients tend to lose body heat due to lowered metabolism and
20 as a result of exposure of internal body organs or tissue, e.g. in an abdominal or thoracic cavity, to ambient air.

Hypothermia is experienced by more than 60% of patients after surgery, and in some surgical procedures, e.g. open heart surgery, hypothermia is experienced by more than 90% of adult patients.

Hypothermia can cause various severe physiological problems including cardiac morbidity, coagulopathy, impaired immune function, impaired wound healing, shivering, altered pharmacokinetic properties of drugs, etc.

Hyperthermia, namely increase in body temperature above normal levels, may also cause various physiological disorders and if extreme, may be life threatening.

The clinical need to provide means for body temperature control has long been recognized.

MicroClimate Systems Inc., Stanford, MI, U.S.A., markets a series of portable personal cooling systems (sold under the trademarks **KOOLVEST**, **KOOLJACKET**, **KOOLBAND**, **KOOLPAID** and others) which are intended for use by healthy persons who perform a physical activity in a hot environment (see Internet <http://www.microclimate.com/prodline.html> or <http://www.microclimate.com/work.html>). The system consists of a garment (it may be a vest, jacket, skull cap, a cervical collar, etc.) with tubing embedded therein in which water flows propelled by a battery-powered pump. Water passes through ice or through a cooling device before entering the tubing within the garment. The user can control the pump rate, the temperature, etc. A similar product line is also provided by Mallinckrodt Inc., St. Louis, MO, U.S.A. (see the Internet at <http://www.mallinckrodt.com/ccd>) and others.

A similar system is disclosed in U.S. Patent 4,807,447 (Macdonald *et al.*). The unique feature of this system is that the person's breathing is used to operate the refrigerant compressor.

Various systems making use of garments, pads or blankets with heat transfer elements, e.g. conduits embedded therein, are disclosed in U.S.

Patents 3,738,367, 4,094,357, 4,094,367, 4,149,541, 4,844,072, 5,184,612 and 5,269,369. However, due to various physiological reasons, realized only in accordance with the present invention and which will be specified further below, none of the above systems provides adequate control of body
5 temperature of the individuals in general, and of patients following surgery before undertaking general anesthesia in particular.

There is also a need for control of body temperature in veterinary medicine, particularly the control of body temperature during surgery under general anesthesia. Animals, and particularly small animals, occasionally die
10 following surgery, owing to uncontrolled changes in body temperature.

GENERAL DESCRIPTION OF THE INVENTION

In the following, the term "*core temperature*" will be used to denote the temperature within the body, namely that of the internal organs and tissue. Core temperature is typically measured through the rectum ("*rectal*
15 *temperature measurement*") but may also be measured by inserting probes through a variety of other body cavities, e.g. mouth, nasal or ear temperature probes. The term "*surface temperature*" will be used to denote the temperature of the external body surface, (which may be that of the skin or, where the skin has been removed, e.g. in a burn injury, that of the most
20 external layers). It should be noted that surface temperature may vary between different body portions. The surface temperature may be measured by a variety of temperature probes including, for example, an infrared sensor measuring infrared emission from a specific skin portion, probes attached to the skin such as a thermo-couple devices, thermistor, etc.

25 In accordance with the present invention, it has been realized that a major deficiency of prior art thermoregulatory devices is that these do not sufficiently reconcile the fact that the body is not a passive heat conductor but rather employs intrinsic dynamic physiological thermoregulation mechanisms which can change the heat transfer properties between the body's core and the

periphery. For example, when exposed to a low temperature, there is a vasoconstriction of peripheral blood vessels, thus reducing blood flow to the periphery and thereby reducing heat transfer between the periphery and the body's core. In other situations there is vasodilatation resulting in increased
5 blood flow to the periphery above normal levels thus bringing an increase in heat transfer rate between the body's core and the periphery.

In accordance with the invention, a system and method for the control of body temperature is provided. The system and method of the invention allows controlled cooling of body temperature, controlled heating, as well as
10 regulating an individual's body temperature to remain at a desired set temperature. It is a unique feature of the invention that it takes into consideration the complexity of the heat transfer regiment from the skin to the body's core. This complexity is manifested by dynamic heat transfer properties, namely physiological changes which can alter the rate in which
15 heat can be transferred between the skin and the body's core. Such heat transfer dynamics (HTD) may be determined by a variety of means, as will be illustrated further below.

In accordance with the invention there is provided a system for controlling an individual's body core temperature (BCT) comprising:

- 20 - a heat exchanger for transferring heat to or removing heat from portions of the individual's body surface;
- at least one BCT-sensing device for measuring the individual's actual BCT (aBCT) and emitting an aBCT data signal;
- at least one sensing device for measuring a parameter indicative
25 of the heat transfer dynamics (HTD) between the body surface and the body's core, and emitting an HTD data signal; and
- a control module for receiving data signals from measuring devices, comprising the aBCT data signal and the HTD data signal, and for emitting a control signal for controlling heat exchange properties of said heat

exchanger as a function of the data signals and the desired body core temperature (dBCT).

The heat exchange may either be provided with an internal heat or cold producing capability, e.g. including a Peltier effects modules, or the heat
5 exchanger may be linked to at least one source of cold and/or hot fluid, which fluid then circulates between such source and the heat exchanges to transfer heat/cold between the exchanger and said source.

By another aspect, the present invention provides a method for controlling internal body temperature of an individual, comprising the
10 following steps:

- (a) defining a desired body core temperature (dBCT);
- (b) providing a heat exchanger and bringing it into contact with at least a portion of the individual's external body surface, for heat transfer to or heat removal from the body portion;
- 15 (c) continuously measuring parameters including at least the actual body core temperature (aBCT) and a parameter indicative of the heat transfer dynamics (HTD) between the body's surface and the body's core; and
- (d) in a processor, receiving data signals corresponding with the measured parameters, comparing the aBCT with the dBCT, defining based
20 thereon whether there is a need for heating or cooling and emitting a control signal controlling heat transfer properties of said heat exchanger based on the aBCT/dBCT difference and on said HTD.

The control of the heat exchange properties of said heat exchanger may involve change of the heat transfer properties between the heat
25 exchanger and the body surface which may be achieved, for example, by changing the heat conductance parameters between the body's surface and the skin, e.g. by pumping or removing air into or from air pockets disposed between heat radiating/heat absorbing members within the heat exchanger and the skin; or preferably, by changing the temperature of the heat
30 exchanger, which may either be a reduction in the extent of heating or

cooling, halting the heating or cooling operation, or reversing the heating or cooling operation into cooling or heating, respectively. In reversing, the heat exchanger acting first as a heat source will be switched to become a heat sink, or *vice versa*, thus reversing the direction of heat transfer.

5 The heat exchanger may, for example, comprise electric heating/cooling devices, e.g. Peltier devices and others. However, in accordance with a preferred, non-limiting, embodiment of the invention, the heat exchanger is of a kind comprising one or more conduits or fluid transfer medium for passing the heat control fluid therethrough, for transferring heat to or
10 absorbing heat from the individual's body surface. The fluid, which is typically, though not exclusively, a liquid, e.g. water, may be driven through the conduits or medium by a pump or any other suitable device therefor. Such fluid thus circulates between the heat exchanger and a heat and/or cold source. The heat exchanger is typically flexible to allow it intimate contact
15 with a body surface for efficient heat transfer therewith.

 In addition to the above noted measuring devices (the BCT sensing device and the device for measuring a parameter indicative of said HTD), the system may further comprise one or more devices for measuring temperature of the circulating fluid and for emitting data signal relating thereto to the
20 controller. At times, where the system comprises two or more such devices, at least one of which may serve as an inlet temperature sensing device for measuring temperature of the fluid as it enters the at least one conduit or fluid transfer medium, and at least one other may serve as an outlet temperature sensing device for measuring temperature of the fluid as it exits the at least
25 one conduit or fluid transfer medium. The temperature drop (ΔT) between the garment's inlet and the outlet is a very good indicator of said HTD, since this information, together with information on the fluid's flow rate, permits an accurate calculation of the heat transfer between the heat exchanger and the body, which depends on said HTD. Thus, in accordance with a preferred

embodiment said ΔT and the fluid flowrate are used as an HTD-indicating parameter.

The heat exchanger of the invention is typically a garment which is worn over a portion of the individual's body. Typically, the garment may be
5 designed so as to cover at least about 30%, preferably at least about 40% of the body's surface. In this way, the system of the invention effectively stabilizes an individual's body temperature, at a desired body core temperature, within a minimal tolerance. Such a garment may have different forms depending on its intended use. For example, the garment may be
10 designed for use by individuals performing hard labor under extreme hot conditions, for the purpose of cooling their body. For such a purpose the garment has to be relatively flexible so as to limit, as little as possible, the free movement of the individual. By another example, the garment may be designed for medical use, either for the purpose of reducing core temperature
15 of individuals having a disease with a very high fever, for the purpose of increasing core body temperature of hypothermic individuals or for both. A currently preferred embodiment of the invention is the application of the system for control of body temperature of patients during or after general anesthesia. For this purpose the heat exchanger, typically in the form of a
20 garment, may have a variety of openings permitting access for the performance of various surgical procedures, for parental administration of drugs or fluids or for drainage of body fluids, (e.g. excretions or blood).

One example of the use of the system and method of the invention in accordance with the above referred embodiment, is in open heart surgery.
25 Open heart surgery typically involves cooling of the body temperature to about 32°C. During such surgery the heart's activity is temporarily arrested and the blood is circulated through an artificial heart-lung apparatus. Following such surgery, there is a need to increase the body temperature to normal temperature as rapidly as possible, since maintaining such a core body
30 temperature for prolonged time periods may be damaging, at times even life

threatening. Today's medical practice involves, towards the end of the surgery, heating of the blood as it circulates through the artificial heart-lung apparatus. However, this heating practice has proven insufficient, as the body's core is not sufficiently heated in this way, and once the blood is
5 disconnected from this apparatus and allowed to recirculate through the reactivated heart, the blood temperature immediately drops. Heating in such procedures is typically performed today by the use of heated blankets, blowing of hot air on the individual, etc. Overall, the methods available today do not allow an efficient monitoring and control of body core temperature. In
10 accordance with the invention, the body core temperature may be controllably cooled during the initial phases of the surgery, then maintained at about 32°C while applying heating or cooling as needed, and then eventually controllably heated at the end of the surgery to reach normal body temperature.

Generally, the system and method of the invention may be used in
15 control of patient's body temperature during the perioperative period in a wide range of different surgeries.

As will no doubt be appreciated, a heat exchanger in the form of a garment may typically be designed to have various forms and sizes, to meet specifications of individuals of various ages, weights, agendas, etc., or to
20 meet specific requirements of a specific medical procedure.

In addition to use for humans, particularly in human medicine, the method and system of the invention may also find a wide range of applications in veterinary medicine. The same problems of resuming normal body temperature, as well as a controlled cooling during surgery, are also
25 encountered in veterinary medicine. As will be appreciated, the heat exchanger, typically in the form of a pad, a blanket or garment, may be designed to have different shapes, depending on the type of animal, the type of surgery, etc.

A system of the invention for use in the operation room, may typically
30 be designed for exchange of data with other instruments present in the

operation room, e.g. import of data relating to blood temperature from heart-lung apparatus, import of data relating to heartbeat or blood pressure from respective measuring devices, etc.

The sensing device for measuring a skin parameter indicative of said
5 HTD (hereinafter referred to at times as "*HTD device*"), may, in accordance with the one embodiment, include a device for measuring a temperature at a skin portion proximal to a skin portion on which the heat exchanger is applied. The HTD may then be determined, for example, by either one or both of

10 (i) determining the rate of temperature change at said skin portion following heating or cooling of adjacent skin portions by the heat exchanger, or

(ii) by assessing the rate of change of temperature difference between the skin portion and the core during heating or cooling of the body.

15 Said HTD device may, in accordance with another embodiment of the invention, consist of the aforementioned at least two sensing devices for measuring temperature of the fluid as it enters the at least one conduit in the heat exchanger and the temperature as it exits from the at least one conduit. The controller, thus receiving at least two data signals relating to the
20 measured temperature, then calculates said HTD based on the inlets or outlet temperature differential and on the fluid flow rate, which is either determined by the controls or measured by an appropriate measuring device.

In accordance with other embodiments, said HTD device is adapted for measuring a parameter indicative of said HTD, which parameter may be one
25 of a variety of skin and peripheral blood flow parameters. These may be determined by many techniques, e.g. by echo doppler signal techniques, skin conductance, peripheral blood pressure, skin temperature, skin color, etc.

One major feature of the invention relates to the measurements of said heat transfer dynamics (HTD), and taking the heat transfer dynamics into
30 consideration in the heat control regime of the individual. Specifically, when

the HTD parameters point to the occurrence of vasoconstriction, any applied cooling should be temporarily halted or reduced. At times, it is advantageous also to reverse the heat transfer mode, temporarily heat in a cooling mode. This means that a cooling mode will involve occasional heat pulses timed and
5 patterned according to said HTD.

The system may have a user interface permitting a user to enter a dBCT, namely a temperature set point of the system. The user interface may further comprise control means allowing selective operation of the system in either an automatic mode, namely in a mode permitting both cooling or
10 heating depending on the direction or deviation of the aBCT from the dBCT. In addition, the control means may also typically allow to select a heat only mode or a cool only mode.

Typically, the heating will be limited so that the temperature at the surface of the heat exchanger which is in touch with the body surface, will not
15 exceed maximum temperature, e.g. a temperature of about 40°C and not to fall below a minimum temperature, e.g. about 15°C.

In order to be effective in cooling or heating, the heat exchanger, typically in the form of a garment, has to be fitted onto the individual's skin. At times, there is a need to wear such a garment for a prolonged period of
20 time, and this may give rise to a risk of pressure wounds. In order to circumvent this problem in accordance with one embodiment of the invention, the heat exchanger has two or more individually flow-controlled flow sub-systems, and these sub-systems may then be used intermittently, namely, one system being inflated with fluid and used, while the other being
25 deflated and thus not exerting pressure on the skin; and *vice versa*. In accordance with another embodiment, the fluid transfer to the garment is temporarily halted for periods of several seconds to minutes in order to reduce the pressure onto the skin thus reducing currents of pressure.

In accordance with one embodiment of the invention, the system
30 comprises an electric in-line fluid heating/cooling unit and the circulation

fluid is directed to flow through said unit for heating or cooling. Heating or cooling of the fluid in such a unit may also be achieved by means of an auxiliary circulatory heat transfer fluid through the intermediary of a heat exchanger within said unit. In accordance with another embodiment, the system comprises at least one cold fluid reservoir and at least one hot fluid reservoir and comprises a fluid flow control system for selectably drawing fluid from these reservoirs. One advantage of having independent hot and cold fluid reservoirs, is that the switching between heating and cooling modes can be rapid.

10 In a system comprising independent hot fluid and cold fluid reservoirs, the flow control system is preferably adapted to permit return fluid to flow back into the reservoir from which it was drawn. It is preferred that during switching from a cold to hot fluid or *vice versa*, the original fluid will flow initially to the reservoir from which it was drawn, and only after the warm
15 fluid has been exploited will the returned fluid be directed to the other reservoir. Otherwise, the cold reservoir may be heated or the hot reservoir cooled. This may be achieved by having a temperature sensing device measuring the temperature of the fluid flowing out of the heat exchanger and only when the device measures an abrupt temperature change, will the flow
20 control system begin to direct the fluid to the new reservoir.

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described by way of a non-limiting example only, with occasional reference to the annexed drawings:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a garment in accordance with an embodiment of the invention.

Fig. 1B is an enlargement of the region marked "B" in Fig. 1A with the two external layers being partially separated for illustrative purposes.

Fig. 2 illustrates a top view of a laid-open garment, for use in the system in accordance with an embodiment of the invention.

Fig. 3 is a schematic illustration of the garment of Fig. 1, applied to a patient.

Fig. 4 is a side elevation of the patient with the garment of Fig. 3.

Fig. 5 shows a garment in accordance with another embodiment of the invention, in an open state with the patient lying thereon provided with an adhesive matrix.

Fig. 6 is a schematic general illustration of a system in accordance with the invention.

Fig. 7 is a schematic side elevation of the system of Fig. 6.

Fig. 8 is a principal schematic illustration of a system in accordance with another embodiment of the invention.

Figs. 9A and 9B show a schematic block diagram of the algorithm operating in the system in accordance with one embodiment of the invention. (Fig 9B is continuum of Fig. 9A).

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

A top view of a garment 2 in accordance with one embodiment of the invention shown in an open layout can be seen in Fig. 1. Garment 2 is designed for fitting over a person's torso. Garment 2, as can specifically be seen in Fig. 1B, is formed with two external layers 4 and 6 defining between them a fluid passage space 7. The garment is provided with a fluid inlet 8 and a fluid outlet 10 for respective fluid ingress and egress into and out of the

fluid passage space. The garment is provided with a partition 12 which defines a fluid flow-path which is represented schematically by arrowed line 14. This fluid is typically water but may also be any other suitable liquid, e.g. alcohol, oil, etc., and may also, in other embodiments be a gas, e.g. air.

5 As can further be seen in Fig. 1B, the garment is formed with a matrix of welded points 16 where the two external layers 4 and 6 of the garment 2 are welded one to another. In use the pressure of the fluid forces the two layers away from one another filling fluid in the space between the welded points. The welded points ensure the structural integrity of the two layers and
10 further ensure some resistance to fluid flow and consequently substantially even distribution of fluid flow through the garment's entire fluid passage space 7. As will no doubt be appreciated, the internal structure of the garment is but an example. By other embodiments the garment may comprise two external layers sandwiching a porous matrix between them; may comprise
15 tubes or other conduits embedded or defined therein by welded lines; etc.

A top view of a garment in accordance with another embodiment shown in open layout, and generally designated 20, can be seen in Fig. 2. The garment 20 has openings 22 and 24, which allow, when the garment is fitted on a person, access to the underlying skin portion, e.g. for skin temperature
20 measurements, for injection, etc. Rather than openings 22 and 24 the garment may also be provided with flaps serving a similar purpose. The garment is provided with several cuts 28, 30 and 32 for fitting of the garment on the individual, as can be seen in Fig. 3. The garment which may have a similar internal structure to that shown in Fig. 1B, is formed with weld lines 34A,
25 34B, 35, 36A and 36B which together define a fluid flow path as represented by arrowed lines 37A, 37B, 37C and 37D extending between the fluid inlet 44 and outlet 46. In this case, the garment is structured such that the chest and abdominal portion of the individual are left open, thus rendering this garment suitable for chest and abdominal surgery. For other surgical applications, the

garment may assume a variety of different shapes. In addition, the garment may also be provided in various sizes for fitting individuals of different weights, gender, age, etc.

The garment may be made of a variety of different materials including
5 fabrics, plastic materials, etc. The garment should preferably be flexible and elastic to allow it to fit over an individual's body. The outer layer of the fabric may be coated with a heat insulating material, to prevent heat transfer to the external environment. In addition, the garment may have an internal soft lining such as felt, in order to avoid occurrence of pressure wounds.

10 Furthermore, as will be explained with reference to Fig. 5, the garment may be provided with an internal fluid absorbent layer.

The garment may be made for multiple use, or occasionally may be made disposable. The garment made for multiple use should be made of such materials as to allow its sterilization by any one of a plurality of sterilization
15 means known *per se*.

As can be seen in Figs. 2-4, fluid inlet/outlet tubings 44, 46 are connectable to a liquid temperature control unit 48 (seen in Fig. 4).

In order to allow easy fixing and removal of the garment, it is typically provided with detachable fixing means, such as a hook and pile (e.g.
20 Velcro™) type attachment members 50.

Fig. 5 is a planar view of a garment 120 in accordance with another embodiment of the invention, still in an open position, prior to fixing it over the patient's body. In this figure, like reference numerals to those of Figs. 2-4 were used, with a "100" index (namely with a "1" prefix) and the reader is
25 referred to the description relating to Figs. 2-4 for their explanation. Further seen in Fig. 5, are matrices 50 which are made of an absorbent material. Typically, such a matrix has a fluid permeable layer, and a hygroscopic material capable of absorbing liquids and retaining them within. Such matrices of liquid absorbent properties, are readily known in the art, and a
30 detailed description of their structure goes beyond the present writing.

Also seen in Fig. 5, are skin-temperature sensing probes **60** and **62** and a rectal temperature probe **64** for measuring core temperature. In addition, other types of temperature measuring devices may be provided, e.g. an intra-ear temperature measuring device, an infrared sensor for measuring skin temperature, an oral temperature measuring device for measuring core temperature, etc. As explained above, the skin temperature is measured, in accordance with one embodiment of the invention, in order to determine the heat transfer dynamics (HTD) of the skin. For the same purpose, as an alternative to measurement of skin temperature, other parameters may be measured which include skin color, skin conductance, peripheral blood pressure, temperature drop of the heating or cooling fluid (as will also be outlined below), as well as any other parameters which can give an indication of occurrence of vasoconstriction or vasodilatation.

In addition, advantageously, temperature sensing devices **70** and **72** for measuring inlet and outlet fluid temperature may also be provided. Such information may also be utilized for the rate of heat transfer between the heat exchanger, namely the garment, and the skin in order to assess the HTD.

A schematic representation of the system in accordance with another embodiment of the invention can be seen in Figs. 6 and 7. A patient **80** as shown herein is provided with a garment **220** (shown schematically as a rectangle in Fig. 5). In Figs. 6 and 7, the same reference numerals to those used before are used, where applicable, with "200" index. Garment **220** is provided with a fluid inlet **244** and outlet **246** and with a continuous fluid conduit or a continuous porous space **240** between them, embedded in garment **220**. A plurality of sensing devices shown herein schematically as component **90**, transmit data signals reflecting the patient's physiological parameters, are transmitted to controller **94**.

The system of this embodiment is adapted for both heating or cooling the patient. By one embodiment, hot fluid and cold fluid are provided from

respective, independent hot and cold fluid reservoirs 96 and 98. Each of the reservoirs has respective fluid inlets 101, 102 and respective fluid outlets 103, 104. The system is provided with a pump 105 for propelling fluid within the system.

5 The system is provided with two flow control valves 106 and 107, for selectively transferring return fluid to or drawing fluid from one of the two reservoirs. Pump 105 and flow control valves 106 and 107, are electrically operated by controller 94 through command lines, 108, 109 and 110, respectively.

10 When switching from a heating mode to a cooling mode or *vice versa*, the flow control valves are switched accordingly. In accordance with one embodiment of the invention, the fluid outlet 246 is provided with a heat sensor 272 which allows switching of the returning fluid from one reservoir to another only upon sensing an abrupt temperature change by sensing
15 device 272, which then transmits a data signal to controller 94 which in turn causes flow control valve to switch. The arrangement is such that the first flow control valve to be switched will be valve 107 and if, for example, the switch was from a cold fluid to a hot fluid, valve 106 will continue to direct the return fluid into reservoir 102 and only upon registering an abrupt
20 temperature drop by sensor device 272 will be return fluid be channeled to reservoir 96.

 In other embodiments, such as that shown in Fig. 8, heating and cooling of the working fluid is carried out "*on-line*" by a heat pump operating as heater/cooler unit. Such a unit which may, for example, be provided with
25 Peltier effect heat pumps, may easily be controlled to either heat or cool the fluid passing therethrough.

 A schematic description of a system in accordance with an embodiment of the invention can be seen in Fig. 8. Here again, like reference to those used previously in the description, with a "300" index were used and

the reader is referred to the previous description for explanation of their function. Controller 394 is provided with a display 311 to display the registered parameters, e.g. measured core temperature, the measured skin temperature, the desired core temperature, flow rate, fluid temperature, etc. In addition, controller is provided with a control panel 312 and a processor 313. The processor 313 receives data signals from all sensing devices (core temperature measuring device 364, skin temperature measuring device 362, an optional infrared skin-temperature measuring device 314, and others). In addition, the processor also receives temperature data from inlet and outlet fluid temperature sensing devices 370 and 372 and temperature registered in heating/cooling device 315 by means of a sensor 316. Device 315 may for example be a Peltier effect heat pump, as known *per se*. In addition, the controller controls the flow rate of pump 308 via command line 317 and controls the temperature of device 315 through line 318.

On the basis of the various data signals registered by the processor, and implementing various algorithms designed in accordance with the general teaching of the invention, e.g. that exemplified below, the flow rate of the fluid and/or the temperature of the fluid may be controlled. Various servo loops may be implemented through processor 313 for proper control of the various parameters.

Fig. 8 shows an algorithm, by way of blocked diagram, of the various computational steps of the algorithm operating in a processor in accordance with the embodiment of the invention. Contrary to previous figures, the reference numerals used in this figure have no bearing to previously used reference numerals.

In a first decision step 410 the system is initiated and integrity is checked. If the system detects a fault, in any of its components, a system shut down sequence 412 is initiated. In the initiation step, the various operational modes are set. These may be automatic, heating only or cooling only modes.

Other parameters which may be set by the user are minimal and maximal permitted temperature of the heat transfer liquid, typically water to prevent tissue damage as well as discomfort to the patient, particularly when not under general anesthesia.

5 In the next two decision making steps 414 and 416, the actual water temperature (designated in the figure as "*WATER TEMP*") is compared to the maximally allowed water temperature ("*HIGH TEMP*") and to the minimal allowed water temperature ("*LOW TEMP*"). In case in step 414 the water temperature is found to be above the *HIGH TEMP* limit, a cooling
10 sequence 418 is initiated, and in the case the water is found in step 416 to be too cold, the heating sequence 420 is initiated.

At the next decision step 422, a mode is selected based on the user's input, between cooling only mode, heating only mode or automatic mode, designated 424, 426 and 428, respectively.

15 In the first decision step 430 of the heating mode, the body core temperature ("*CORE TEMP*") is compared to the desired body core temperature ("*SET POINT*"). Where the body core temperature is found to be above the set point, the system is primed to enter to a standby mode 432, namely the heating function is terminated. During the standby mode, the core
20 temperature is continuously measured and compared to the set point.

When the core temperature is determined to be below the set point, the water temperature is compared to the high temperature at 434 and if the water temperature is below the high temp, the heat mode 420 is initiated. If the water temperature is found to be above high temp, the system is primed again
25 to enter into a standby mode 432.

In the first decision making step 440 of the cooling mode 424, the body core temperature is compared to the set point and if found to be below the set point, the system is primed into standby mode 432. If the core temperature is below the set point, the system determines whether

vasoconstriction of the skin has occurred 442. If there is no vasoconstriction, the cooling mode progresses into a next decision making step 444 where the water temperature is compared to the minimal allowed temperature. If water temperature is less than *LOW TEMP* then the system is primed to enter into a standby mode 432, and if above, the cooling sequence 418 is initiated.

In step 442, if vasoconstriction is found to have occurred (i.e. low heat conductance between the core and the periphery) notwithstanding the fact that there is a cooling mode, a heating sequence is initiated. When vasoconstriction is determined to have ceased, the cooling sequence is reinstated.

In a first decision making step 450, of the automatic mode 428, the core temperature is compared to the set point, if found to be below the set point, the system enters the heating mode 426. If the core temperature is found to be below the set point, the sequence proceeds to the next decision making step 452 and there, if the core temperature is found to be above the set point, the cooling sequence 424 is initiated. If the core temperature is found to be below the set point, the system is shifted towards the standby mode.

In the algorithm described above, the only parameter controlled is the water temperature. It should be appreciated, that in other embodiments, parameters such as flow rate of the heat transfer fluid may also be controlled. In addition, various other parameters, such as blood temperature, based on data imported from artificial heart-lung apparatus, may also be factored in the system's output.

As will be appreciated, the determination of the occurrence of vasoconstriction may be based on a variety of parameters, as noted above in the description, making use of data received from one or more of the above described sensing devices.

CLAIMS:

1. A system for controlling an individual's body core temperature (BCT) comprising:
 - 5 - a heat exchanger for transferring heat to or removing heat from portions of the individual's body surface;
 - at least one BCT-sensing device for measuring the individual's actual BCT (aBCT) and emitting an aBCT data signal;
 - at least one sensing device for measuring a parameter indicative
10 of the heat transfer dynamics (HTD) between the body surface and the body's core, and emitting an HTD data signal; and
 - a control module for receiving data signal from measuring devices, comprising the aBCT data signal and the HTD data signal, and for emitting a control signal for controlling heat exchange properties of said heat
15 exchanger as a function of the data signals and a desired body core temperature (dBCT).
2. A system according to Claim 1, wherein said heat exchanger comprises one or more conduits for passing heat control fluid therethrough, for transferring heat to or absorbing heat from the individual's body surface.
- 20 3. A system according to Claim 2, wherein the heat exchanger is coupled to a device for circulating the heat control fluid through the conduits.
4. A system according to Claim 2 or 3, comprising one or more devices for measuring temperature of the circulating fluid and for emitting data signal relating thereto to the controller.
- 25 5. A system according to any one of claims 2-4, wherein said fluid is a liquid.
6. A system according to any one of the preceding claims, wherein said heat exchanger is in a form of a garment to be worn over a portion of the body.

7. A system according to any one of the preceding claims, for use in control of a patient's body temperature during or after general anesthesia or in a perioperative period.
8. A system according to Claim 7, wherein said heat exchanger is in a
5 form of a garment to be worn over a portion of the body.
9. A system according to Claim 8, wherein said garment has openings permitting access for surgical procedures, for parental administration or for drainage of fluids.
10. A system according to Claim 7 or 8, wherein at least a portion of the
10 garment is fitted with a removable and flexible liquid absorbent matrix.
11. A system according to any one of the preceding claims, wherein said sensing device for measuring a parameter indicative of said HTD includes a device for measuring temperature at a skin portion proximal to a skin portion on which the heat exchanger is applied, and determination of the HTD is
15 based on *assessing the rate of temperature change*.
12. A system according to any one of claims 1-10, wherein said sensing device for measuring said skin parameter includes a device for measuring temperature at a skin portion proximal to a skin portion on which the heat exchanger is applied, and determination of the HTD is based on determining
20 the rate of change of temperature difference between said skin portion and the body core.
13. A system according to Claim 4 or 5, comprising at least one inlet temperature sensing device for measuring temperature of the fluid as it enters the at least one conduit, and at least one outlet temperature sensing device for
25 measuring temperature of the fluid as it exits the at least one conduit, these sensing devices being coupled with the controller and emitting respective data signals thereto; the controller calculating said HTD based on the inlet/outlet temperature differential and on the fluid flow rate.
14. A system according to any one of the preceding claims, wherein said
30 surface parameter comprises a parameter selected from the group consisting

of body's surface temperature, skin color, peripheral skin blood pressure, electrical skin, conductance of the skin, echo doppler signal.

15 15. A system according to any one of the preceding claims, wherein during heating or cooling, the heating or cooling operation, respectively, is occasionally temporarily halted or reversed to respective cooling or heating.

16. A system according to Claim 15, wherein halting or reversing of heating or cooling is automatically performed when determined HTD indicates reduction in heat transfer properties between the periphery and the body's core, signifying the occurrence of vasoconstriction.

10 17. A system according to any one of the preceding claims wherein the controller has a cooling operational mode, a heating operational mode and an automatic operational mode for heating or cooling depending on the difference between core temperature and desired core temperature.

18. A system according to any one of the preceding claims, comprising a
15 user control interface permitting a user to set the dBCT, or set the system to operate in either of a cooling operational mode, a heating operational mode or an automatic operational mode.

19. A system according to any one of the preceding claims, wherein the temperature of the heat exchanger is maintained between a minimum and a
20 maximum temperature to avoid tissue damage in view of exposure to access heating or cooling.

20. A system according to any one of the preceding claims, wherein the heat exchanger is formed with at least two individually flow-controlled flow sub-systems.

25 21. A system according to any one of Claims 2-5, comprising at least one electric fluid heating/cooling unit and the fluid is directed to flow through said unit.

22. A system according to any one of Claims 2-5, comprising at least one cold fluid reservoir and at least one hot fluid reservoir and a fluid flow control
30 system for selectively drawing fluid from these reservoirs.

23. A system according to Claim 22, wherein the fluid flow control system permits returned fluid to flow back into the reservoir from which it was drawn.

24. A system according to Claim 22 or 23, comprising at least one
5 temperature sensing device measuring temperature of the fluid flowing out of said heat exchanger, and upon change of drawn fluid from one reservoir to another the fluid flow control system initially directs the return fluid to said one reservoir and when said sensing device senses a substantial temperature change it directs the return fluid to said other reservoir.

10 25. A method for controlling internal body temperature of an individual, comprising the following steps:

- (a) defining a desired body core temperature (dBCT);
- (b) providing a heat exchanger in contact with at least a portion of the individual's external body surface, for heat transfer to or heat removal
15 from the body portion;
- (c) continuously measuring parameters including at least the actual body core temperature (aBCT) and a parameter indicative of the heat transfer dynamics (HTD) between the body's surface and the body's core;
- (d) in a processor, receiving data signals corresponding with the
20 measured parameters, comparing the aBCT with the dBCT, defining based thereon whether there is a need for heating or cooling and emitting a control signal controlling heat transfer properties of said heat exchanger based on the aBCT/dBCT difference and on said HTD.

26. A method according to Claim 25, wherein the heat transfer to and from
25 the body portion is achieved by transfer of heat control fluid through said heat exchanger.

27. A method according to Claim 26, wherein said fluid is a liquid.

28. A method according to any one of Claims 25-28, for controlling of a patient's body temperature during or after general anesthesia.

30 29. A method according to any one of Claims 25-28, comprising continuously monitoring a temperature at a skin portion proximal to a skin

portion in which the heat exchanger is applied, and determining said HTD based on the rate of temperature change at said skin portion.

30. A method according to Claims 25-28, comprising continuously monitoring temperature at a skin portion proximal to a skin portion in which
5 the heat exchanger is applied, and determining said HTD based on determining the rate of change of temperature at a difference between said skin portion and the body core.

31. A method according to Claim 26 or 27, comprising continuously monitoring the inlet fluid temperature, namely the temperature of the fluid
10 entering said heat exchanger, and the outlet fluid temperature, namely the temperature of the fluid as it exits from said heat exchanger, and said HTD is calculated based on the inlet/outlet temperature differential and on the fluid flow rate.

32. A method according to any one of Claims 25-31, wherein said
15 parameter indicative of said HTD is selected from the group consisting of body's surface temperature, skin color, peripheral skin blood pressure, electrical skin, conductance of the skin, echo doppler signal.

33. A method according to any one of Claims 25-32, wherein during heating or cooling, the heating or cooling operation, respectively, is
20 occasionally temporarily halted or reversed to respective cooling or heating.

34. A method according to Claim 33, wherein the halting or reversing of the heating or cooling, is performed when said parameter is indicative of said HTD, indicates the occurrence of vasoconstriction.

1/8

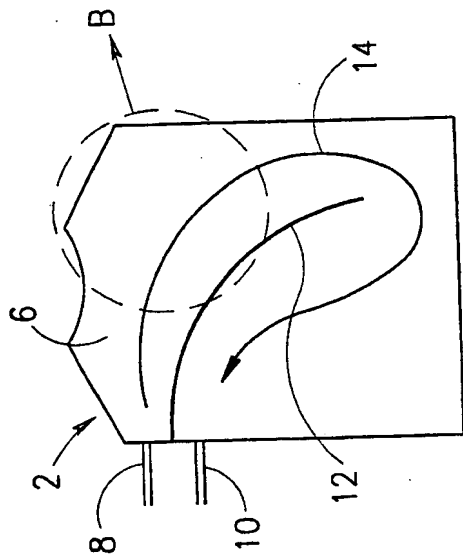


FIG. 1A

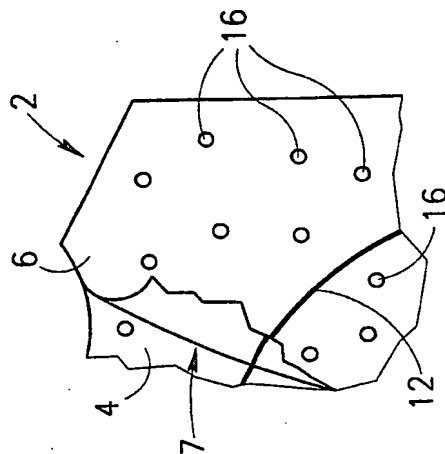


FIG. 1B

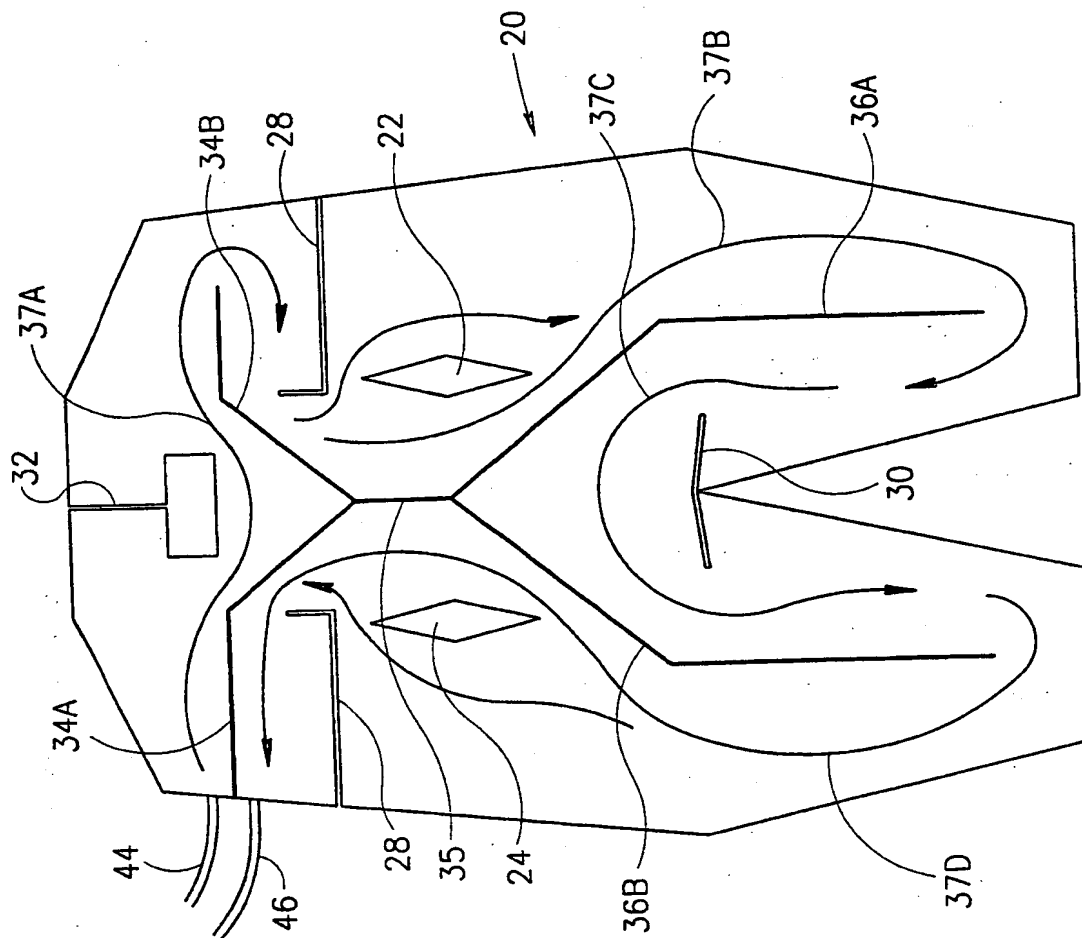


FIG. 2

2/8

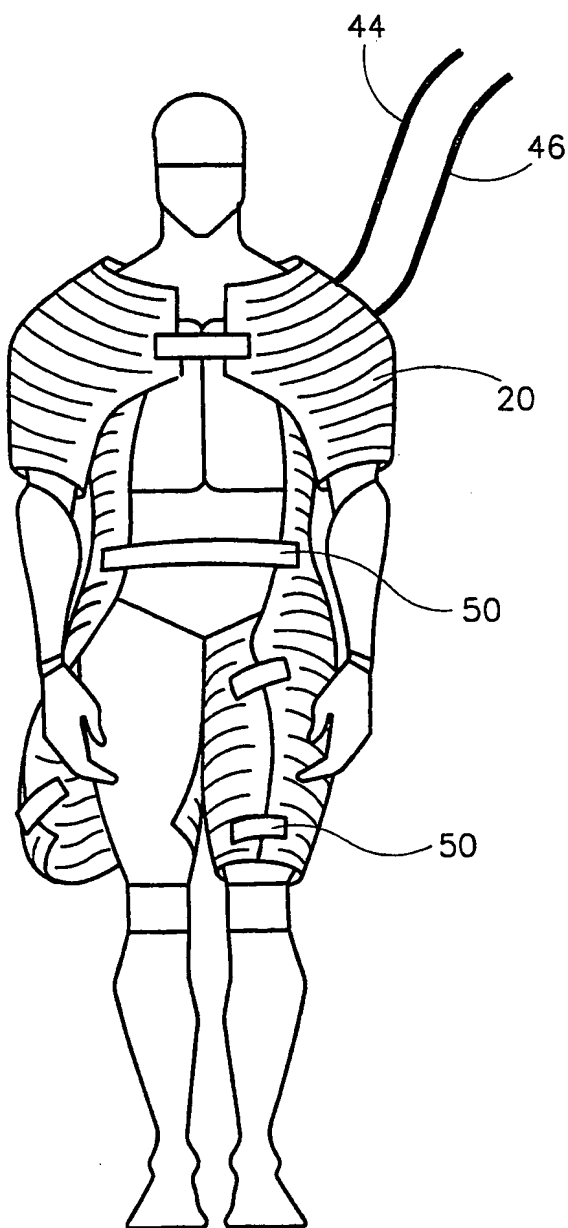


FIG.3

3/8

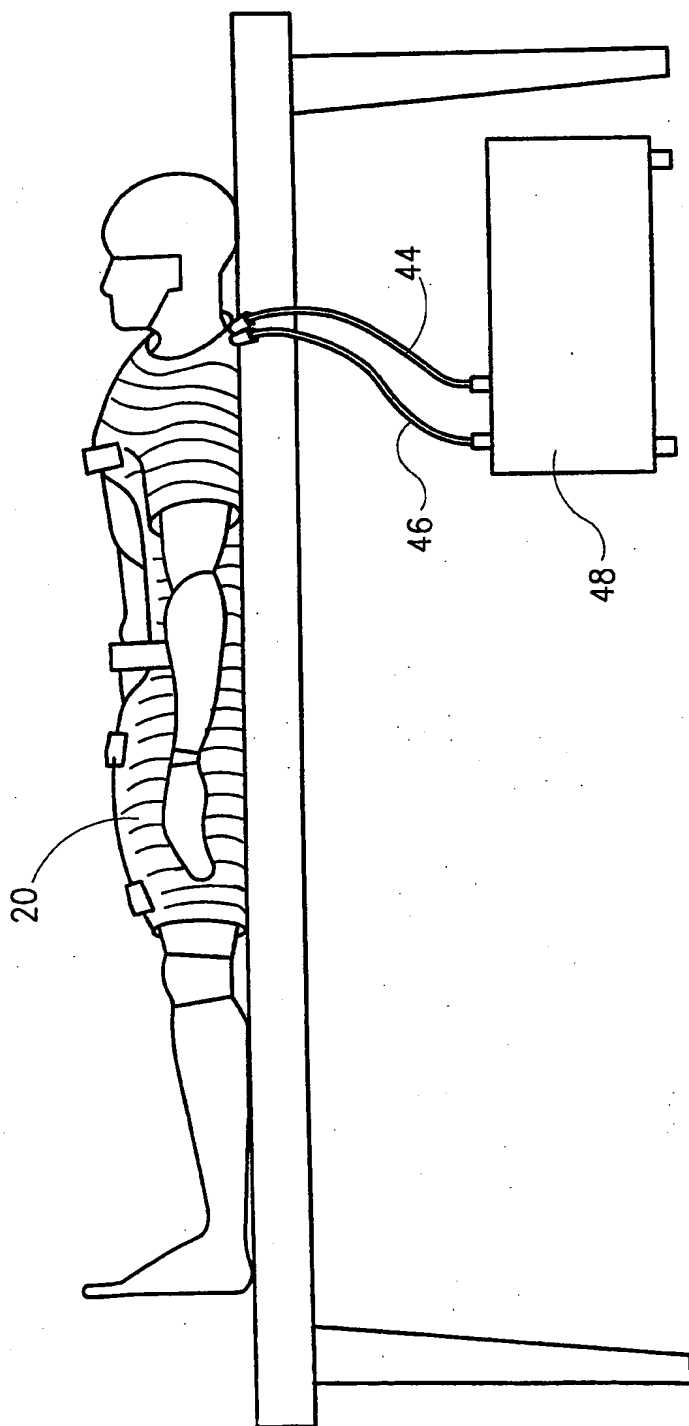


FIG. 4

4/8

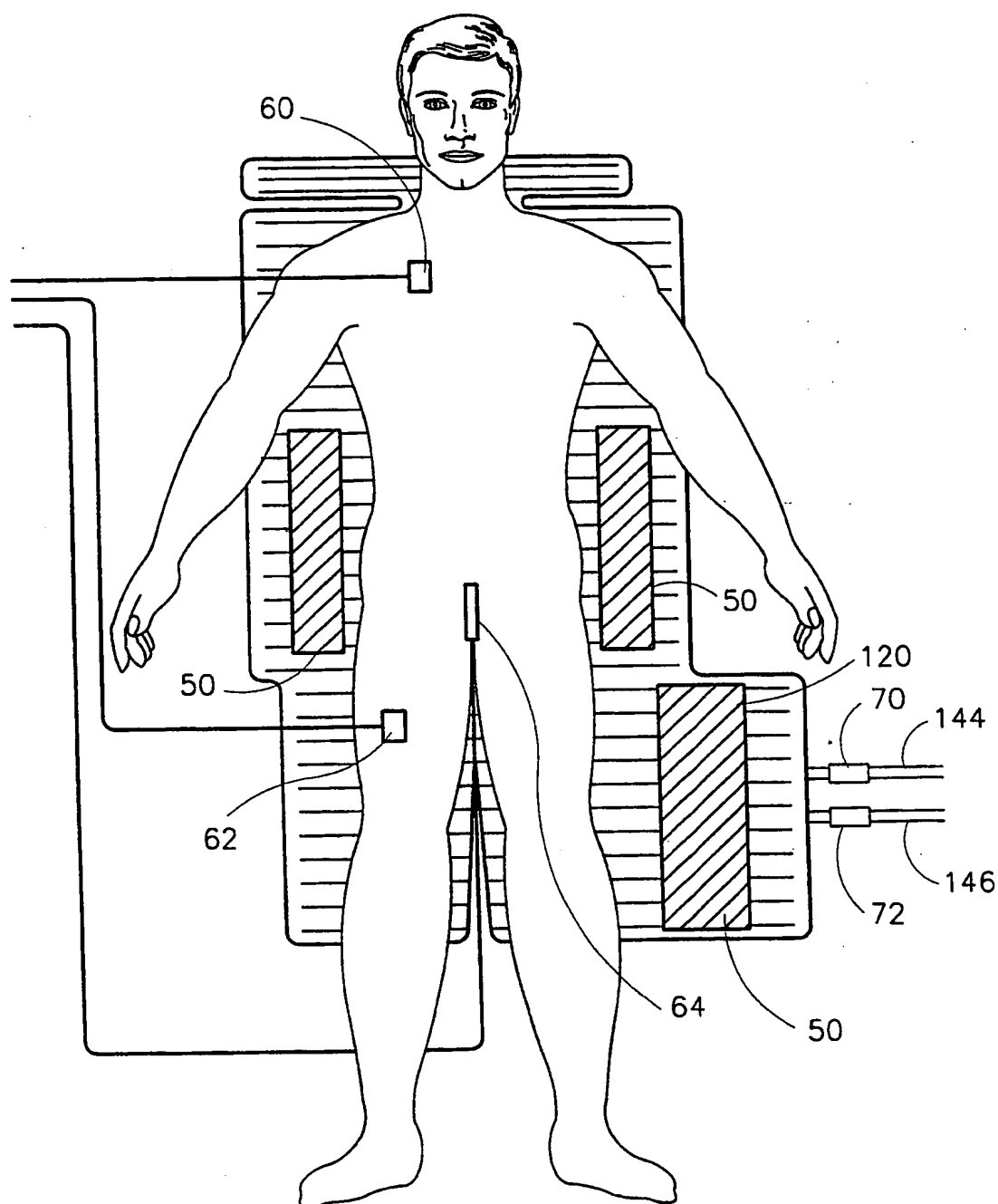


FIG.5

5/8

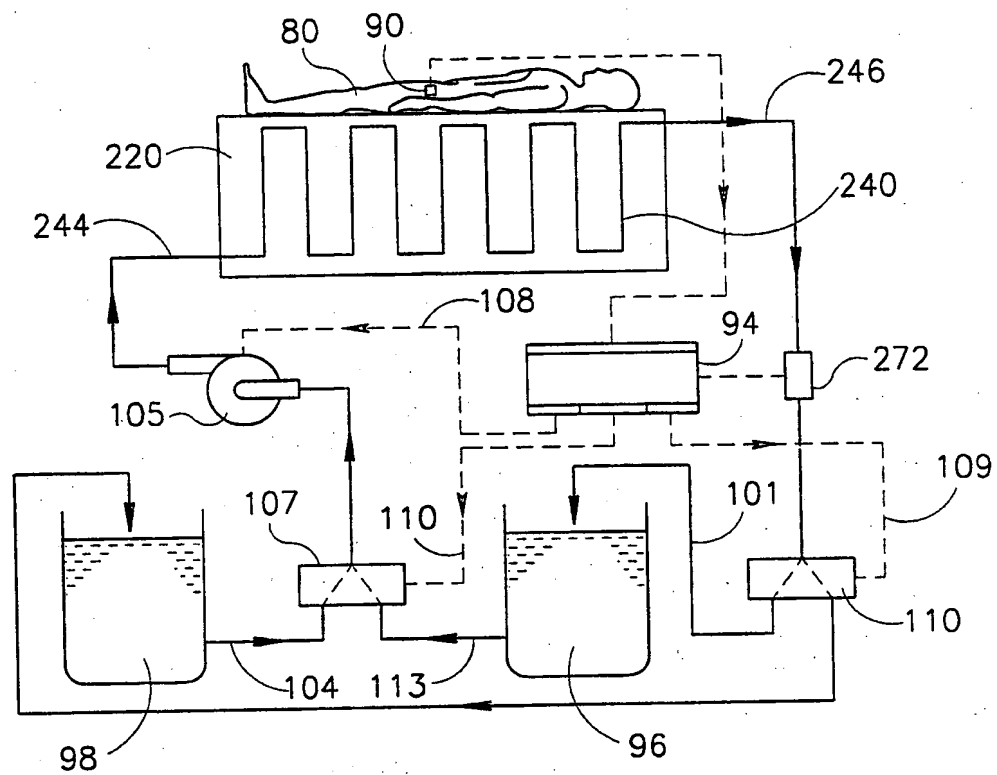


FIG. 6

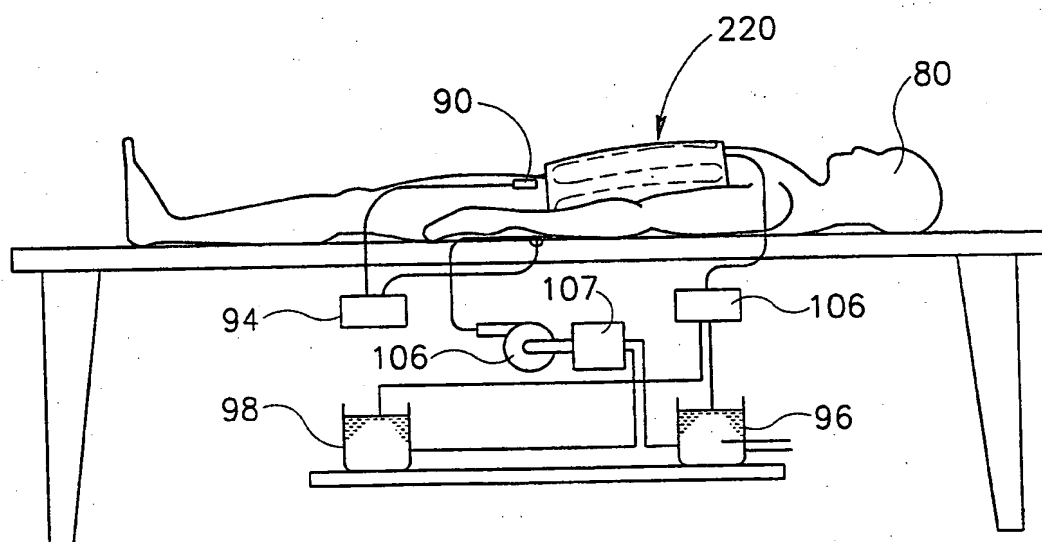


FIG. 7

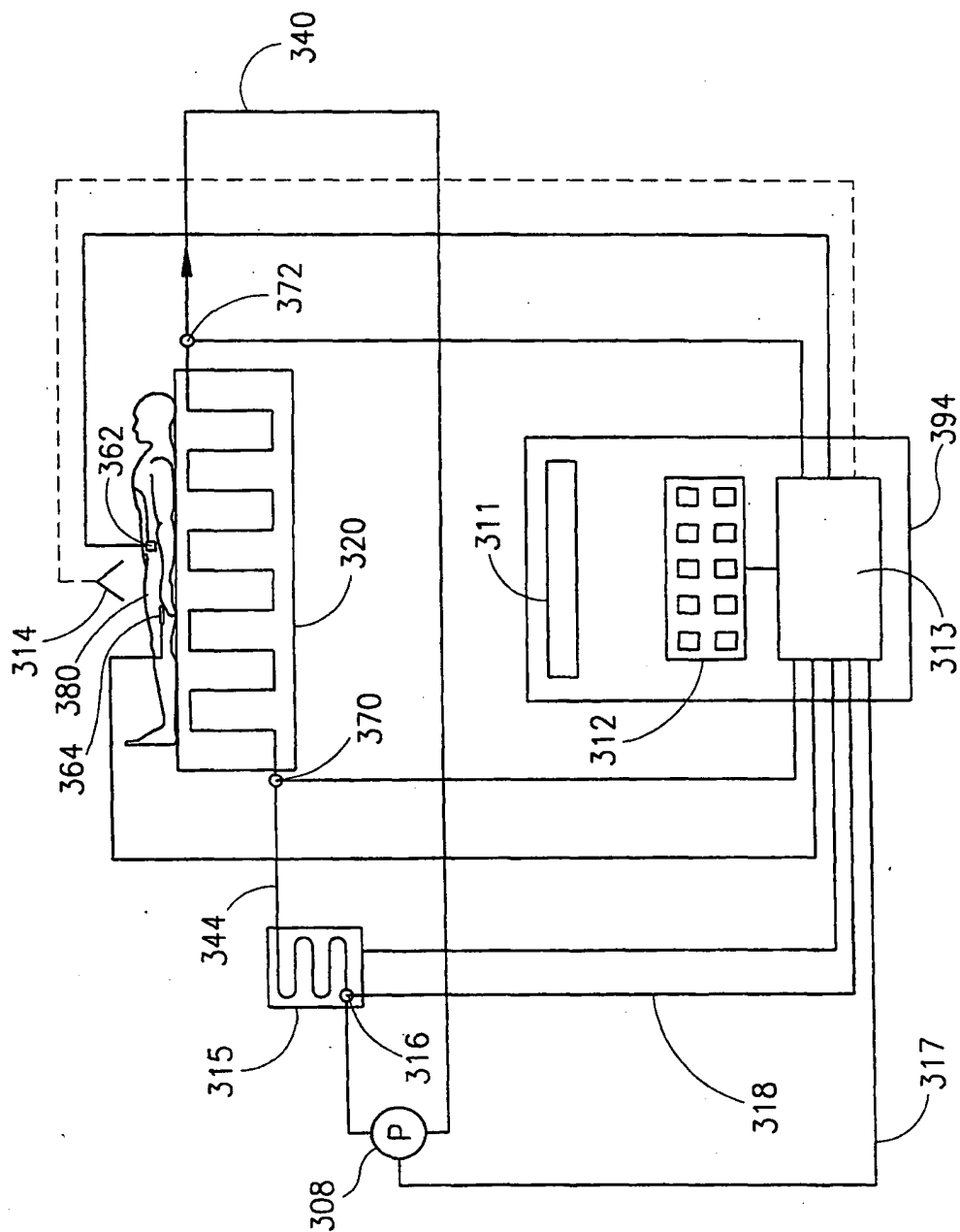
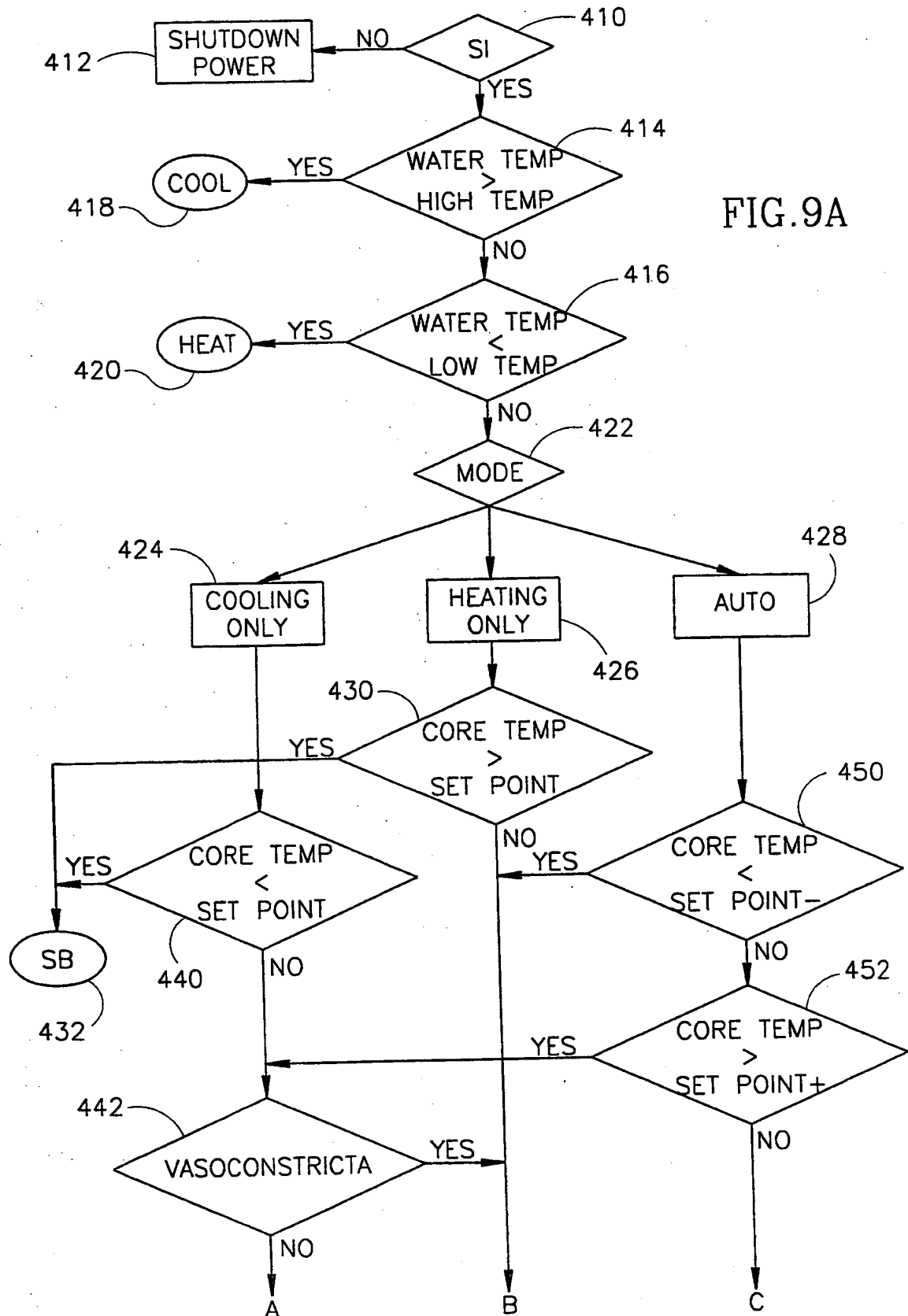


FIG. 8

7/8



8/8

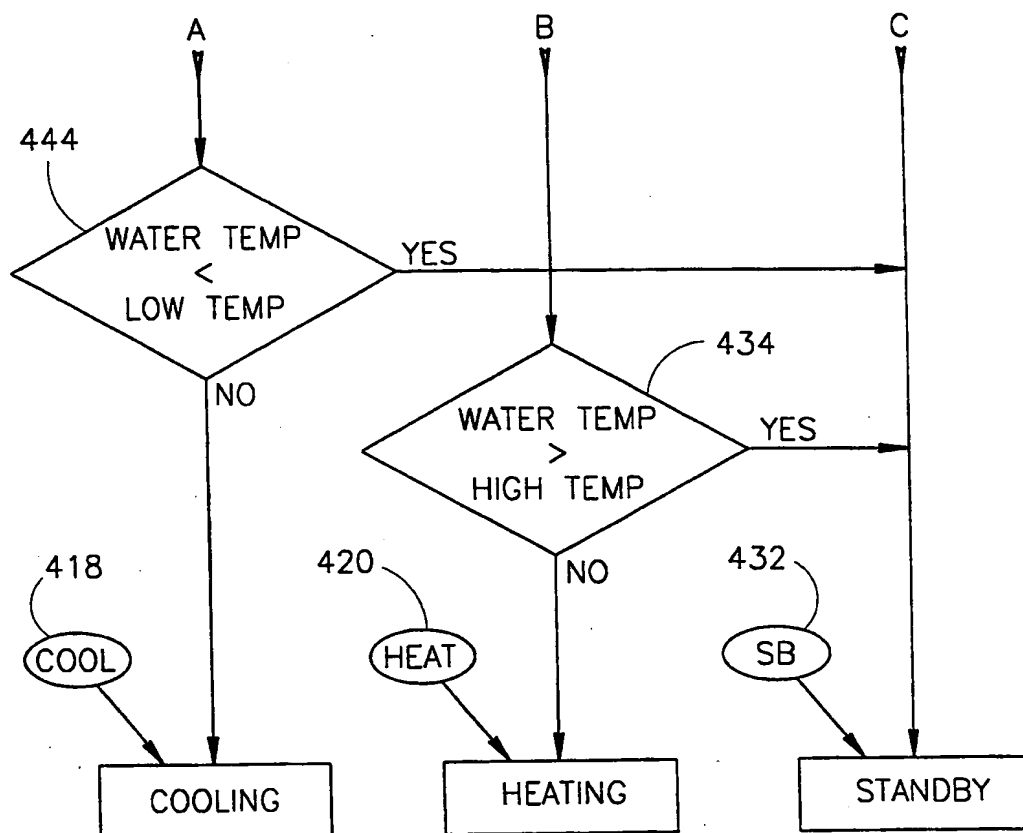


FIG. 9B

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 99/00059

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A41D A62B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 411 541 A (BELL ANTHONY H G ET AL) 2 May 1995 see column 12, line 25 - line 65 ---	1-5,15, 17,18, 20-24
A	US 4 691 762 A (ELKINS WILLIAM ET AL) 8 September 1987 see column 8, line 8 - line 61 see column 14, line 65 - column 15, line 14 ---	1-6,13
A	WO 96 26693 A (SHANNON COOL LIMITED ;KOLEN PAUL T (US); FORD THOMAS D (US)) 6 September 1996 see page 9, line 17 - line 29 see page 12, line 19 - page 13, line 19 --- -/--	1-5,13

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

20 May 1999

Date of mailing of the international search report

31/05/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Petter, E

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 99/00059

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 097 829 A (QUISENBERRY TONY) 24 March 1992 see column 5, line 3 - line 26 see column 5, line 57 - column 6, line 13 ---	1-5,13
A	GB 2 263 872 A (S I IND LIMITED ;KING RICHARD JONATHAN (GB)) 11 August 1993 see column 1, line 32 - line 40 see column 2, line 14 - line 27 ---	1-5,11, 19
A	US 5 609 619 A (POMPEI FRANCESCO) 11 March 1997 see page 4, line 5 - line 12 see page 7, line 36 - page 8, line 8 see page 10, line 6 - line 15 -----	1,7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 99/00059

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 25-34
because they relate to subject matter not required to be searched by this Authority, namely:
RULE 39.1 (iv) PCT - METHOD FOR TREATMENT OF THE HUMAN OR ANIMAL BODY BY THERAPY
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

SERIAL NO.:
 APPLICANT:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.:

HOLLYWOOD, FLORIDA 33055
 TEL. (888) 252-1100

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 99/00059

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5411541 A	02-05-1995	AU 7273294 A WO 9504508 A	28-02-1995 16-02-1995
US 4691762 A	08-09-1987	NONE	
WO 9626693 A	06-09-1996	IE 950163 A AU 5179096 A CA 2214269 A EP 0812168 A US 5865841 A	27-12-1995 18-09-1996 06-09-1996 17-12-1997 02-02-1999
US 5097829 A	24-03-1992	NONE	
GB 2263872 A	11-08-1993	NONE	
US 5609619 A	11-03-1997	US 5292347 A WO 9111974 A	08-03-1994 22-08-1994

DOCKET NO: W80-41953

SERIAL NO: _____

APPLICANT: Lothar Gluderer

LERNER AND GREENBERG P.A.

P.O. BOX 2480

HOLLYWOOD, FLORIDA 33022

TEL. (954) 925-1100